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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/810,783	03/16/2001	Raphael C. Wong	BRA4.PAU.02	9163

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EXAMINER

NGUYEN, BAO THUY L

ART UNIT	PAPER NUMBER
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1641

DATE MAILED: 06/12/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/810,783

Applicant(s)

WONG, RAPHAEL C.

Examiner

Bao-Thuy L. Nguyen

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-- The MAILING DATE of this communication appears on the cover sheet with the corresponding address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 March 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 10-18 and 23-32 is/are pending in the application.
- 4a) Of the above claim(s) 30-32 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 10-18 and 23-29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

1. Applicant's amendment filed on March 31, 2003 has been received. Claims 1-9 and 19-22 have been canceled. Claims 30-32 have been added. Claims 10-18 and 23-32 are pending.
2. The text of those US codes not found in this office action may be found in a previous office action.
3. All rejections not reiterated herein below are withdrawn in view of the amendment to the claims.

Election/Restrictions

4. Newly submitted claims 30-32 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: claim 30 is directed to a device comprising two separate regions for detecting the presence of both a drug of abuse and an adulterant in two separate samples of body fluid. Such a device is different from the device of claim 10 where the same sample is tested for both a drug of abuse and an adulterant.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 30-32 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Claim Rejections - 35 USC § 102

5. Claims 10-18 and 23-29 are rejected under 35 U.S.C. 102(e) as being anticipated by Lee (US 2002/0001854 A1) for reasons of record that are reiterated herein below.

Lee discloses a device for detecting analytes in a sample while simultaneously evaluating whether the analyte sample has been adulterated or otherwise compromised. The device of Lee comprises one or more analyte test strips and integrity pads separate from the analyte test strip via a fluid barrier. Each of the analyte test strip is separated from the next within a housing by raised spacer, and the portion of the housing that overlies the test and control zones is transparent to permit viewing of the results. See page 1. The fluid barrier between the analyte test strip and the integrity pad includes a physical gap or a hydrophobic film disposed on a carrier membrane. Thus, sample fluid that has not passed through analyte test is brought into contact with integrity determinant pad via passage through the carrier membrane. The carrier membrane is physically separated from analyte test strip by a layer of non-bibulous paper. See pages 4 and 5.

Response to Arguments

6. Applicant's arguments filed March 31, 2003 have been fully considered but they are not persuasive.

Applicant asserts that the instant device differ from the device of Lee because unlike Lee, the instant adulterant test strips are detached from the drug test strips. Applicant asserts that Lee teaches a device where the adulterant test strips and the drug test strips are coupled to the same carrier membrane that directs fluid to the integrity determinant pad, and that the instant adulterant test strips and the drug test strips are not coupled to any common membrane.

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Fluid communication is completely prevented between the adulterant test strips and the drug test strips.

These arguments have been fully considered but are not deemed to be persuasive.

Although it is true that Lee teaches a device where the drug test strips and the adulterant test strips are coupled to a common membrane, Lee also teaches that these two test strips are separated from each other by a fluid barrier zone including a physical gap, a hydrophobic film or an absorbent pad imbued with a hydrophobic material (see page 4, first column, paragraphs [0048] and [0049]). Clearly, Lee teaches a device where the adulterant test strips and the drug test strips are placed in two separate regions and are detached (i.e. not in physical contact) from each other. The fact that the drug test strip and the adulterant test strip are placed on a common membrane is irrelevant since the open "comprising" language of the instant claims is inclusive or open-ended and does not exclude additional, unrecited elements. See, e.g., *Genentech, Inc. v. Chiron Corp.*, 112 F.3d 495, 501, 42 USPQ2d 1608, 1613 (Fed. Cir. 1997) ("Comprising" is a term of art used in claim language which means that the named elements are essential, but other elements may be added and still form a construct within the scope of the claim.); *Moleculon Research Corp. v. CBS, Inc.*, 793 F.2d 1261, 229 USPQ 805 (Fed. Cir. 1986); *In re Baxter*, 656 F.2d 679, 686, 210 USPQ 795, 803 (CCPA 1981); *Ex parte Davis*, 80 USPQ 448, 450 (Bd. App. 1948) ("comprising" leaves "the claim open for the inclusion of unspecified ingredients even in major amounts"). Since Lee teaches all essential components of the claimed apparatus and method of making, Lee is seen to anticipate the claimed invention.

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Conclusion

7. THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

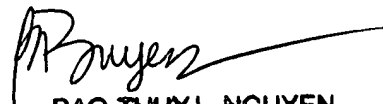
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao-Thuy L. Nguyen whose telephone number is (703) 308-4243. The examiner can normally be reached on Monday, Wednesday and Thursday from 9:00 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (703) 305-3399. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

June 12, 2003


BAO-THUY L. NGUYEN
PRIMARY EXAMINER